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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,548	02/05/2002	David W. LaFleur	PZ024P1C1	3544

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/062,548	LAFLEUR ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 2. NOTE: Applicants have amended the withdrawn claim 19 to depend from an allowed polypeptide of claim 56. However, if said Amendment were to be entered, a new issue under 35 U.S.C. 112, second paragraph would be raised as follows: Claim 19 is drawn to a method of diagnosing any pathological condition or a susceptibility to any pathological condition in a subject be the measuring of the presence or amount of the polypeptide in a biological sample. The method is confusing under the 112, second paragraph because it is unclear whether the actual level of the polypeptide serves as a marker for a pathological condition or its susceptibility or the presence of the polypeptide serves as a marker for the pathological condition or its susceptibility. Further, the claim is indefinite because it is unclear what pathological condition said marker is to detect. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject, wherein said pathological condition is a testes cancer, does not reasonably provide enablement for a method of diagnosing any pathological condition or a susceptibility to any pathological condition in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification provides a page description of the gene product, wherein said encoded polypeptide is described as SEQ ID NO: 97. The specification only provides that the gene product was primarily expressed in human testes tumor (or cancer). The specification speculates that because the claimed polypeptide is of lymphoid in origin, such polypeptide could be useful as an agent for any immunological disorders ranging from arthritis to AIDS. While applicants have identified the immunogenic portion of the polypeptide within SEQ ID NO: 97, the specification does not give any examples nor guidance to a skilled artisan in the art of immunology, to use the polypeptide as a diagnostic marker other than for testes cancer. Therefore, one skilled in the art would be required to conduct an undue amount of experimentation in determining whether the claimed polypeptide is first present and if so, how much of it is expressed in every single listed plurality of diseases disclosed in the specification, resulting in an undue amount of experimentation. Additionally, the objection of claims 67-71 under 37 CFR 1.175 as being a substantial duplicate of claims 51-55, made in the Office Action mailed on February 9, 2004 is maintained for the reasons of record. Applicants' arguments presented in the Amendment received on March 26, 2004 have been fully considered but they are not found persuasive for the following reasons. Applicants appear to speculate that the claims "may be" different based on the section of the specification, wherein the section states that the DNA sequences generated by sequencing reaction can contain sequencing errors and these errors exist as misidentified nucleotides, or as insertions or deletions of nucleotides in the generated DNA sequence, thus causing frame shifts in the reading frames of the predicted amino acid sequence. However, the claims stand on their own merits, and absent evidence to the contrary that the "cDNA" identified as "HHEPU32" deposited under ATCC Deposit No. 209603 encodes a protein other than SEQ ID NO: 97, the claims are determined to be duplicative in their scope.

4-7-04

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/8/04